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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,443	03/07/2001	Suneel K. Gupta	ARC 2863 N1	7756

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,443	GUPTA ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. US 5,912,268, in view of Oshlack et al. US 5,965,161.

Guittard discloses a method for administering a controlled release dosage form comprising oxybutynin, its racemate, its R-enantiomer and it's S-enantiomer (see abstract, column 2, lines 31-48; and column 12, lines 40-45). Guittard also teaches administering oxybutynin for incontinence therapy, *e.g.*, increasing the urinary bladder capacity, and diminishing the frequency of uninhibited contractions of the detrusor muscles (relaxing bladder muscles), (see column 3, lines 24-28; and column 4, lines 13-21).

Guittard does not expressly teach the dosage form, which would exhibit the same plasma concentration in fed state as well as fasted state.

Oshlack teaches a sustained release unit dosage form comprising anti-spasmodic active agent suitable for once-a-day product without a food effect (see abstract; and column 13, lines 8-10). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release dosage form of Guittard using the sustained release dosage form in view of the teaching of Oshlack to obtain the claimed invention, because Oshlack teaches a sustained release dosage form that release the drug in such a rate that plasma concentrations are maintained within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 5, lines 1-4), because Guittard teaches a dosage form that reduces and/or eliminates the unwanted influences of the gastrointestinal environment of the use and still provides controlled release of oxybutynin over time, and because Guittard teaches a dosage form that provides release of oxybutynin at plasma concentrations within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 13, lines 5-10). The expected results would be a sustained release dosage form of oxybutynin that is free of food effect.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. US 5,912,268, in view of Morella et al. US 5,378,474.

Guittard does not expressly teach the dosage form, which would exhibit the same plasma concentration in fed state as well as fasted state.

Morella teaches a sustained release dosage form comprising smooth muscle relaxant agent, such as oxybutynin hydrochloride (see abstract, and column 5, lines 34-36). Morella further teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65). The dosage form further shows no evidence of dose dumping, and the relative bioavailability of the active ingredient is not compromised by food so that compliance will improve as the product may be taken without regard to meals (column 7, lines 35-40). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release dosage form of Guittard using the sustained release dosage form in view of the teaching of Morella to obtain the claimed invention, because Morella teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65), because Morella teaches the sustained release dosage form can be taken without regard to meals (column 7, lines 35-40), because Guittard teaches a dosage form that reduces and/or eliminates the unwanted influences of the gastrointestinal environment of the use and still provides controlled release of oxybutynin over time, and because Guittard teaches a dosage form that provides release of oxybutynin at plasma concentrations within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 13, lines 5-10). The expected results would be a sustained release dosage form of oxybutynin that is free of food effect.

Claims 15, 16, 21-25, 39-43 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. US 5,378,474, in view of Lukkari et al. (Eur. J. Pharmacology).

Morella teaches a sustained release dosage form comprising smooth muscle relaxant agent, such as oxybutynin hydrochloride (see abstract, and column 5, lines 34-36). Morella further teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65). The dosage form further shows no evidence of dose dumping, and the relative bioavailability of the active ingredient is not compromised by food so that compliance will improve as the product may be taken without regard to meals (column 7, lines 35-40).

Morella teaches oxybutynin among a number of other drugs.

Lukkari specifically teaches the effect of food on the bioavailability of oxybutynin from a controlled release tablet (page 221). Lukkari concludes that the effect of food is of limited clinical significance, and the pharmacodynamic effects are not to be altered by eating (page 223). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the sustained release dosage form of Morella to obtain a sustained release dosage form of oxybutynin in view of the teaching of Lukkari, because the references teach the desirability to achieve a sustained release dosage form containing oxybutynin that is free of food effect.

Response to Arguments

Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. The 103(a) rejections over Guittard in view of Oshlack; Guittard in view of Morella; and Morella in view of Lukkari are maintained for the following reasons:

Applicant argues that independent claims 15, 24, 33, and 42 all recite an oxybutynin release rate that accomplishes a desired outcome. Applicant admits that it is this release rate that accomplishes the recited similarity of performance under fed and fasted conditions.

However, the limitation from the claim "said dosage form has an oxybutynin release rate that is effective to treat the patient" is a functional language. The claim does not recite the structure of the dosage form, as well as the specific release mechanism that would exhibit the release rate that accomplishes the desired outcome. Thus, applicant's specification is referred to for "said dosage form", as well as "said release rate". It is noted that applicant's specification discloses the same dosage form as that of Guittard '268. The dosage form that uses the same materials, such as hydrogel, that exhibits the same release rate, a zero order rate of release over a period of 24 hours (see applicant's specification pages 7-9; and page 10, lines 20-22). See also Guittard at columns 4-6. At column 5, lines 44-46, Guittard teaches the dosage form delivers oxybutynin at a zero order rate of release over a period of 24 hours. Accordingly, the burden is shifted to applicant to prove that the dosage form taught by Guittard does not exhibit the recited similarity of performance under fed and fasted conditions.

Applicant argues that the office has not shown that the combination of Guittard and Oshlack teaches or suggests all of the claim limitations.

However, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Oshlack recognizes the need for a sustained release unit dosage form useful for smooth muscle relaxant agent, which can be taken without being effected by food (see abstract; and column 13, lines 8-10). Thus, the combination of Guittard and Oshlack suggests a dosage form that exhibits similarity of performance under fed and fasted conditions.

Applicant argues that Morella teaches varying release rate, while Guittard teaches oxybutynin may differ at different points in the GI tract possibly due to presystemic metabolism. Therefore, the combination of Guittard and Morella would produce a dosage from that varies release rate as a function of position within the GI tract coupled with varying absorption of oxybutynin as a function of position within the GI tract. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

It is noted that Morella teaches the desirability of obtaining an oxybutynin dosage form that may be taken without regard to meals (column 7, lines 35-40). Thus, one of ordinary skill in the art would have been motivated to modify the controlled release dosage form of Guittard to obtain an oxybutynin dosage form that may be taken without regard to meals. The expected results would be a sustained release dosage form of oxybutynin that is free of food effect.

It is noted that applicant did not make any argument regarding the rejection over Morella in view of Lukkari et al. (Eur. J. Pharmacology).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

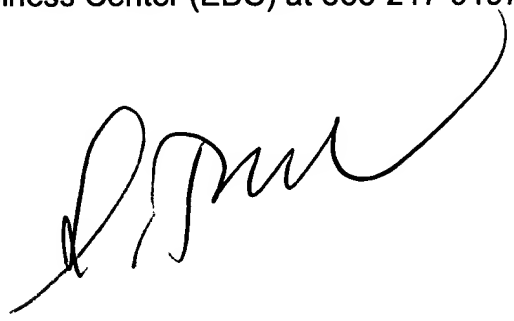
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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